

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF ILLINOIS

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IN RE YASMIN AND YAZ )  
(DROSPIRENONE) MARKETING, SALES ) 3:09-md-02100-DRH-CJP  
PRACTICES AND PRODUCTS LIABILITY )  
LITIGATION ) MDL No. 2100  
)  
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**This Document Relates to:**

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**KERRY SIMS,**

**Plaintiff,**

**3:09-cv-10012-DRH-CJP**

**v.**

**BAYER CORPORATION, BAYER  
HEALTHCARE PHARMACEUTICALS  
INC., BAYER HEALTHCARE, LLC,  
and WALGREEN CO., d/b/a WALGREENS,**

**Defendants.**

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**ANSWER AND ADDITIONAL DEFENSES OF  
DEFENDANT BAYER HEALTHCARE LLC**

Defendant Bayer HealthCare LLC, for its Answer to Plaintiff's Complaint (the "Complaint"), states as follows:

1. Bayer HealthCare LLC admits that YAZ® and Yasmin® are combination oral contraceptives, and that YAZ® and Yasmin® contain drospirenone and ethinyl estradiol. Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 1.
2. Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2.

3. Bayer HealthCare LLC admits, on information and belief, that Plaintiff is a citizen of Illinois, and admits that Belleville, Illinois is in St. Clair County. Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 3.

4. The allegations in paragraph 4 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC admits, on information and belief, that Walgreen Co. is an Illinois corporation. Bayer HealthCare LLC denies the allegations of the third sentence in paragraph 4; because Walgreen Co. was fraudulently joined, it has no citizenship "for diversity purposes" in this case. Bayer HealthCare LLC denies the allegations in the fifth sentence in paragraph 4, and answers further that this case has been properly removed to the United States District Court for the Southern District of Illinois. Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 4.

5. Bayer HealthCare LLC admits that Bayer Corporation is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Bayer HealthCare LLC further admits that Bayer Corporation is the sole member of Bayer HealthCare LLC, that Schering Berlin Inc. is wholly owned by Bayer HealthCare LLC, that Bayer HealthCare Pharmaceuticals Inc. ("BHP") is wholly owned by Schering Berlin Inc., and that BHP is indirectly wholly owned by Bayer Corporation. Bayer HealthCare LLC denies any remaining allegations in paragraph 5.

6. Bayer HealthCare LLC denies the allegations in the first sentence in paragraph 6. Bayer HealthCare LLC admits that Bayer Corporation had conducted business in Illinois, but Bayer HealthCare LLC denies that Bayer Corporation currently sells or distributes products in

Illinois. Because of the vagueness and ambiguity of the remaining allegations in paragraph 6, Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of those allegations.

7. Bayer HealthCare LLC admits that BHCP was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc. Bayer HealthCare LLC further admits that BHCP is a Delaware corporation with its principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Bayer HealthCare LLC denies the remaining allegations in paragraph 7.

8. The allegations in paragraph 8 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC admits that BHCP was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and that BHCP is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc. Bayer HealthCare LLC admits that BHCP, formerly known as Berlex, Inc., formerly known as Berlex Laboratories, Inc., packaged, promoted, marketed, distributed, labeled and sold YAZ® and Yasmin®. Bayer HealthCare LLC denies that BHCP, formerly known as Berlex, Inc., formerly known as Berlex Laboratories, Inc., designed, developed or manufactured YAZ® or Yasmin®. Because of the vagueness and ambiguity of the remaining allegations in paragraph 8, Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of those allegations.

9. Bayer HealthCare LLC admits that BHCP distributes, sells and markets YAZ® and Yasmin® in the United States. Bayer HealthCare LLC denies that BHCP develops, designs, licenses or manufactures YAZ® or Yasmin®. Bayer HealthCare LLC admits that BHCP has sold and distributed its products in Illinois. Because of the vagueness and ambiguity of the

remaining allegations in paragraph 9, Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of those allegations.

10. The allegations in paragraph 10 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC admits, on information and belief, that Berlex Laboratories International, Inc. was a Delaware corporation. Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in the second and third sentences in paragraph 10. Bayer HealthCare LLC denies the remaining allegations in paragraph 10.

11. Bayer HealthCare LLC admits that Bayer HealthCare LLC is a limited liability company formed in Delaware with its principal place of business located at 555 White Plains Road, Tarrytown, New York 10591. Bayer HealthCare LLC denies the allegations in the second and third sentences in paragraph 11. Bayer HealthCare LLC admits that Bayer HealthCare LLC's products are sold and distributed in Illinois. Because of the vagueness and ambiguity of the remaining allegations in paragraph 11, Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of those allegations.

12. Bayer HealthCare LLC admits that the Complaint contains allegations referring to Bayer HealthCare LLC and other entities collectively as "Bayer," "Bayer Defendants" and/or "Defendants," but Bayer HealthCare LLC is not answering the Complaint on behalf of any entity other than Bayer HealthCare LLC, and is not answering allegations that are directed to any entity other than Bayer HealthCare LLC. Bayer HealthCare LLC accordingly denies the allegations in paragraph 12.

13. Bayer HealthCare LLC admits that Plaintiff brings this case seeking certain damages. Bayer HealthCare LLC admits that YAZ® and Yasmin® are prescription oral

contraceptives combining ethinyl estradiol and drospirenone. Bayer HealthCare LLC denies that it designed, manufactured, marketed or distributed YAZ® or Yasmin®. Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of the allegations that Plaintiff ingested and used YAZ® or Yasmin® and that Plaintiff suffered the injuries alleged. Bayer HealthCare LLC denies the remaining allegations in paragraph 13.

14. Bayer HealthCare LLC denies that it manufactured or marketed the birth control pills YAZ® or Yasmin®. Bayer HealthCare LLC admits that YAZ® and Yasmin® are combination oral contraceptives (“COCs”) containing an estrogen and a progestin. Bayer HealthCare LLC further admits that COCs prevent pregnancy through the inhibition of ovulation and changes in the cervical mucus (which increases the difficulty of sperm entry into the uterus) and the endometrium (which reduces the likelihood of implantation). Bayer HealthCare LLC denies the remaining allegations in paragraph 14.

15. Bayer HealthCare LLC admits that the United States Food and Drug Administration (the “FDA”) approved the New Drug Application for Yasmin® in 2001, and that the FDA approved the New Drug Application for YAZ® in 2006. Bayer HealthCare LLC denies any remaining allegations in paragraph 15.

16. Bayer HealthCare LLC admits that YAZ® and Yasmin® contain the estrogen ethinyl estradiol and the progestin drospirenone. Bayer HealthCare LLC further admits that Yasmin® contains 0.03 mg of ethinyl estradiol and 3 mg of drospirenone, and that YAZ® contains 0.02 mg of ethinyl estradiol and 3 mg of drospirenone. Bayer HealthCare LLC denies any remaining allegations in paragraph 16.

17. Bayer HealthCare LLC admits that YAZ® and Yasmin® contain drospirenone, and that Yasmin® was the first birth control pill approved by the FDA for use in the United

States that contained the progestin drospirenone. Because of the vagueness and ambiguity of the remaining allegations in paragraph 17, Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of those allegations.

18. Bayer HealthCare LLC admits that in the 1960s, women using combined oral contraceptives were found to have an increased risk of arterial and venous thromboembolic events, compared to non-pregnant women who were not using combined oral contraceptives. Bayer HealthCare LLC further admits that the risk associated with the use of combined oral contraceptives declined over the period that the estrogen content in combined oral contraceptives was decreased. Because of the vagueness and ambiguity of the remaining allegations in paragraph 18, Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of those allegations.

19. Bayer HealthCare LLC admits that progestins were developed that have been referred to as “second generation” progestins, including levonorgestrel. Because of the vagueness and ambiguity of the remaining allegations in the first sentence in paragraph 19, Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of those allegations. Bayer HealthCare LLC denies the remaining allegations in paragraph 19 as stated. Bayer HealthCare LLC admits that combined oral contraceptives using lower estrogen amounts and second generation progestins were considered to have lower risks of arterial and venous thromboembolic events than combined oral contraceptives using first generation progestins and higher doses of estrogen. Bayer HealthCare LLC denies the remaining allegations in paragraph 19.

20. Bayer HealthCare LLC admits that progestins were developed which have been referred to as third generation progestins. Because of the vagueness and ambiguity of the

remaining allegations in paragraph 20, Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of those allegations.

21. Bayer HealthCare LLC admits that both YAZ® and Yasmin® contain the estrogen ethinyl estradiol, and that ethinyl estradiol has been used in birth control pills approved by the FDA for use in the United States for decades. Bayer HealthCare LLC denies any remaining allegations in paragraph 21.

22. Bayer HealthCare LLC admits that drospirenone is a progestin. Bayer HealthCare LLC further admits that the only birth control pills approved by the FDA for use in the United States that contain drospirenone are Yasmin®, YAZ® and Ocella, and that Ocella is a generic version of Yasmin®. Because of the vagueness and ambiguity of the remaining allegations in paragraph 22, Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of those allegations.

23. Bayer HealthCare LLC denies the allegations in the first sentence in paragraph 23. Bayer HealthCare LLC admits that drospirenone is a different chemical entity than the progestins that were used in second generation combined oral contraceptives and accordingly, drospirenone may have certain effects that are different from those of second generation progestins. Bayer HealthCare LLC denies the remaining allegations in paragraph 23.

24. Bayer HealthCare LLC admits that drospirenone may potentially increase potassium levels in the blood. Bayer HealthCare LLC denies the remaining allegations in paragraph 24.

25. Bayer HealthCare LLC denies that it manufactured, marketed or sold YAZ® or Yasmin®, and accordingly denies that YAZ® and Yasmin® are “Bayer HealthCare LLC’s products”. Bayer HealthCare LLC admits that Yasmin® has been sold in the United States since

2001 and that YAZ® has been sold in the United States since 2006. Bayer HealthCare LLC further admits, on information and belief, that since 2001, the FDA received hundreds of MedWatch forms regarding women reportedly using YAZ® or Yasmin® in which adverse events including death were reported. For a further response, the submission of a MedWatch form to the FDA does not constitute an admission or assertion that the use of YAZ® or Yasmin® caused or contributed to the event that is the subject of the MedWatch form. Bayer HealthCare LLC further responds, on information and belief, that with respect to a number of the reports of adverse events including death submitted to the FDA, the use of YAZ® or Yasmin® has not been confirmed. Bayer HealthCare LLC further responds that all birth control pills approved for use in the United States are associated with reports of adverse events including death. Bayer HealthCare LLC denies the remaining allegations in paragraph 25.

26. Bayer HealthCare LLC admits that the British Medical Journal published an article regarding Yasmin® in April 2002. Bayer HealthCare LLC denies the allegations in paragraph 26 regarding the contents of that article to the extent that they are inconsistent with the language of the article or omit portions of the article. Bayer HealthCare LLC denies the remaining allegations in paragraph 26.

27. Bayer HealthCare LLC admits that the British Medical Journal published a paper regarding Yasmin® in February 2003. Bayer HealthCare LLC denies the allegations in paragraph 27 regarding the contents of that paper to the extent that they are inconsistent with the language of the paper or omit portions of the paper. Bayer HealthCare LLC denies the remaining allegations in paragraph 27.

28. Bayer HealthCare LLC admits, on information and belief, that during the period January 1, 2004 through September 30, 2008, the FDA received over fifty MedWatch forms

regarding women reportedly using YAZ® or Yasmin® in which deaths were reported. For a further response, the submission of a MedWatch form to the FDA does not constitute an admission or assertion that the use of YAZ® or Yasmin® caused or contributed to the event that is the subject of the MedWatch form. Bayer HealthCare LLC further responds, on information and belief, that with respect to a number of the reports of death submitted to the FDA, the use of YAZ® or Yasmin® has not been confirmed. In addition, Bayer HealthCare LLC responds that all birth control pills approved for use in the United States are associated with reports of adverse events including death. Bayer HealthCare LLC denies the remaining allegations in paragraph 28.

29. Bayer HealthCare LLC admits, on information and belief, that during the period January 1, 2004 through September 30, 2008, the FDA received MedWatch forms regarding women in their child-bearing years reportedly using YAZ® or Yasmin® in which deaths relating to a variety of causes were reported. For a further response, the submission of a MedWatch form to the FDA does not constitute an admission or assertion that the use of YAZ® or Yasmin® caused or contributed to the event that is the subject of the MedWatch form. Bayer HealthCare LLC further responds, on information and belief, that with respect to a number of the reports of death submitted to the FDA, the use of YAZ® or Yasmin® has not been confirmed. Bayer HealthCare LLC denies the remaining allegations in paragraph 29.

30. Bayer HealthCare LLC admits, on information and belief, that during the period January 1, 2004 through September 30, 2008, the FDA received MedWatch forms concerning women who reportedly used YAZ® or Yasmin® in which deaths were reported, including women as young as 17 years old. For a further response, the submission of a MedWatch form to the FDA does not constitute an admission or assertion that the use of YAZ® or Yasmin® caused

or contributed to the event that is the subject of the MedWatch form. Bayer HealthCare LLC further responds, on information and belief, that with respect to a number of the reports of death submitted to the FDA, the use of YAZ® or Yasmin® has not been confirmed. Because of the vagueness and ambiguity of the remaining allegations in paragraph 30, Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of those allegations.

31. Bayer HealthCare LLC denies, on information and belief, the allegations in paragraph 31.

32. Bayer HealthCare LLC denies the allegations in paragraph 32.

33. Bayer HealthCare LLC admits that YAZ® and Yasmin® differ from other birth control pills because they contain the progestin drospirenone. Bayer HealthCare LLC denies the remaining allegations in paragraph 33.

34. Bayer HealthCare LLC denies that Berlex Laboratories, Inc. was sold to Bayer HealthCare LLC in 2006. Bayer HealthCare LLC admits that Berlex Laboratories, Inc., now known as BHCP, promoted Yasmin®. Bayer HealthCare LLC admits that a television advertisement for Yasmin® contained the statement that Plaintiff quotes, as well as other statements, which Plaintiff omits. Bayer HealthCare LLC denies the remaining allegations in paragraph 34.

35. Bayer HealthCare LLC admits, on information and belief, that the FDA sent a letter dated July 10, 2003 relating to Yasmin® to Berlex Laboratories, Inc. Bayer HealthCare LLC denies the allegations in paragraph 35 regarding the contents of that letter to the extent that they are inconsistent with the language of the letter or omit portions of the letter. Bayer HealthCare LLC further responds that in July 2003, Bayer HealthCare LLC was not affiliated in any way with Berlex Laboratories, Inc., now known as BHCP. Bayer HealthCare LLC denies the remaining allegations in paragraph 35.

36. Bayer HealthCare LLC admits, on information and belief, that the FDA sent a letter dated July 10, 2003 relating to Yasmin® to Berlex Laboratories, Inc. Bayer HealthCare LLC denies the allegations in paragraph 36 regarding the contents of that letter to the extent that they are inconsistent with the language of the letter or omit portions of the letter. Bayer HealthCare LLC further responds that in July 2003, Bayer HealthCare LLC was not affiliated in any way with Berlex Laboratories, Inc., now known as BHCP. Bayer HealthCare LLC denies the remaining allegations in paragraph 36.

37. Bayer HealthCare LLC denies the allegations in paragraph 37.

38. Bayer HealthCare LLC denies the allegations in paragraph 38.

39. Bayer HealthCare LLC denies the allegations in paragraph 39.

40. Bayer HealthCare LLC denies the allegations in paragraph 40.

41. Bayer HealthCare LLC denies the allegations in paragraph 41.

42. Bayer HealthCare LLC denies the allegations in paragraph 42 to the extent that they are inconsistent with relevant Consent Decrees or omit portions of those Consent Decrees.

Bayer HealthCare LLC denies the remaining allegations in paragraph 42.

43. Bayer HealthCare LLC denies the allegations in paragraph 43.

44. The allegations in paragraph 44 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 44.

45. The allegations in paragraph 45 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 45.

46. The allegations in paragraph 46 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 46.

47. The allegations in paragraph 47 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 47.

48. Bayer HealthCare LLC denies the allegations in paragraph 48.

49. The allegations in paragraph 49 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 49.

50. The allegations in paragraph 50 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 50.

### **FIRST CAUSE OF ACTION**

51. Bayer HealthCare LLC incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

52. Bayer HealthCare LLC denies the allegations in paragraph 52.

53. Bayer HealthCare LLC denies the allegations in paragraph 53.

54. The allegations in paragraph 54 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 54.

55. The allegations in paragraph 55 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 55.

56. The allegations in paragraph 56 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 56.

## **SECOND CAUSE OF ACTION**

57. Bayer HealthCare LLC incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

58. Bayer HealthCare LLC denies the allegations in paragraph 58.

59. Bayer HealthCare LLC denies the allegations in paragraph 59.

60. The allegations in paragraph 60 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 60.

61. The allegations in paragraph 61 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 61.

62. The allegations in paragraph 62 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 62.

63. The allegations in paragraph 63 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 63.

### **THIRD CAUSE OF ACTION**

64. Bayer HealthCare LLC incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

65. The allegations in paragraph 65 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 65.

66. The allegations in paragraph 66 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 66.

67. The allegations in paragraph 67 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 67.

68. The allegations in paragraph 68 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 68.

### **FOURTH CAUSE OF ACTION**

69. Bayer HealthCare LLC incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

70. The allegations in paragraph 70 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies that Bayer HealthCare LLC designed, manufactured, sold or distributed YAZ® or Yasmin®, and denies the remaining allegations in paragraph 70.

71. The allegations in paragraph 71 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 71.

72. The allegations in paragraph 72 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 72.

73. The allegations in paragraph 73 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 73.

74. The allegations in paragraph 74 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 74.

75. The allegations in paragraph 75 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 75.

76. The allegations in paragraph 76 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 76.

#### **FIFTH CAUSE OF ACTION**

77. Bayer HealthCare LLC incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

78. Bayer HealthCare LLC denies the allegations in paragraph 78.

79. Bayer HealthCare LLC denies the allegations in paragraph 79.

80. Bayer HealthCare LLC denies the allegations in paragraph 80.

81. The allegations in paragraph 81 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 81.

82. The allegations in paragraph 82 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 82.

83. The allegations in paragraph 83 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 83.

84. The allegations in paragraph 84 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 84.

85. The allegations in paragraph 85 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 85.

86. The allegations in paragraph 86 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 86.

#### **SIXTH CAUSE OF ACTION**

87. Bayer HealthCare LLC incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

88. The allegations in paragraph 88 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 88.

89. Bayer HealthCare LLC denies the allegations in paragraph 89.

90. The allegations in paragraph 90 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 90.

91. The allegations in paragraph 91 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 91.

92. The allegations in paragraph 92 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 92.

### **SEVENTH CAUSE OF ACTION**

93. Bayer HealthCare LLC incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

94. The allegations in paragraph 94 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 94.

95. The allegations in paragraph 95 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies that either YAZ® or Yasmin® is a “birth control patch” and denies the remaining allegations in paragraph 95.

96. The allegations in paragraph 96 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 96.

#### **EIGHTH CAUSE OF ACTION**

97. Bayer HealthCare LLC incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

98. The allegations in paragraph 98 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 98.

99. The allegations in paragraph 99 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 99.

100. The allegations in paragraph 100 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 100.

101. The allegations in paragraph 101 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 101.

#### **NINTH CAUSE OF ACTION**

102. Bayer HealthCare LLC incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

103. The allegations in paragraph 103 are directed to another defendant and state conclusions of law, and therefore no response is required by Bayer HealthCare LLC. To the

extent that a response is required, Bayer HealthCare LLC denies that YAZ® or Yasmin® are defective or dangerous. Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 103.

104. The allegations in paragraph 104 are directed to another defendant and state conclusions of law, and therefore no response is required by Bayer HealthCare LLC. To the extent that a response is required, Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 104.

105. The allegations in paragraph 105 are directed to another defendant and state conclusions of law, and therefore no response is required by Bayer HealthCare LLC. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 105.

106. The allegations in paragraph 106 are directed to another defendant and state conclusions of law, and therefore no response is required by Bayer HealthCare LLC. To the extent that a response is required, Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 106.

107. The allegations in paragraph 107 are directed to another defendant and state conclusions of law, and therefore no response is required by Bayer HealthCare LLC. To the extent that a response is required, Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 107.

#### **TENTH CAUSE OF ACTION**

108. Bayer HealthCare LLC incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

109. The allegations in paragraph 109 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations regarding the Illinois Consumer Fraud and Deceptive Business Practices Act (the “Act”) to the extent that they are inconsistent with the language of the Act or omit portions of the Act, or are inconsistent with case law interpreting the Act. Bayer HealthCare LLC is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 109.

110. The allegations in paragraph 110 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 110.

111. The allegations in paragraph 111 state conclusions of law to which no response is required. To the extent that a response is required, Bayer HealthCare LLC denies the allegations in paragraph 111.

112. Bayer HealthCare LLC denies that Plaintiff is entitled to any relief, including but not limited to the relief requested in the “Wherefore” clause of the Complaint.

113. Bayer HealthCare LLC denies each and every allegation in the Complaint that relates to or is directed to Bayer HealthCare LLC unless such allegations are expressly admitted in this Answer.

#### **ADDITIONAL DEFENSES**

Discovery and investigation may reveal that one or more of the following additional defenses should be available to Bayer HealthCare LLC in this matter. Bayer HealthCare LLC accordingly reserves the right to assert these separate and additional defenses. Upon completion of discovery, if the facts warrant, Bayer HealthCare LLC may withdraw any of these additional

defenses as may be appropriate. Bayer HealthCare LLC further reserves the right to amend its Answer and defenses, and to assert additional defenses and other claims, as discovery proceeds.

Further answering, and by way of additional defense, Bayer HealthCare LLC states as follows:

1. Plaintiff's Complaint, and each and every count contained therein, fails to state a cause of action or claim upon which relief can be granted.
2. Some or all of Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and/or statutes of repose.
3. Plaintiff's claims are barred, in whole or in part, by laches, waiver and/or estoppel.
4. Plaintiff's claims are barred, in whole or in part, by Plaintiff's failure to mitigate Plaintiff's alleged damages.
5. The acts and omissions of Plaintiff caused and/or contributed to the alleged damages, thereby barring or reducing the amount of recovery under the doctrines of contributory negligence and/or comparative negligence. Plaintiff's recovery, if any, therefore is barred or should be apportioned in accordance with applicable law.
6. The alleged injuries sustained by Plaintiff, if any, were caused, in whole or in part, by pre-existing physical, medical, and/or physiological conditions, for which Bayer HealthCare LLC has no legal responsibility.
7. If Plaintiff suffered injuries as alleged in the Complaint, which is expressly denied, such injuries arose from, and were caused by, risks, hazards, and dangers knowingly assumed by Plaintiff. Plaintiff's recovery accordingly is barred or should be reduced by Plaintiff's assumption of the risk.

8. The injuries claimed by Plaintiff, if any, were the result of an idiosyncratic or allergic reaction to the product.

9. The injuries and damages claimed by Plaintiff, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of Bayer HealthCare LLC was not the proximate and/or competent producing cause of such alleged injuries and damages.

10. The injuries and damages claimed by Plaintiff, if any, are barred or must be reduced because those damages arose from the acts or omissions of persons or entities other than Bayer HealthCare LLC for whom Bayer HealthCare LLC has no legal responsibility.

11. If Plaintiff sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling or other unforeseeable misuse, or use inconsistent with the labeling of the prescription drugs YAZ® and/or Yasmin®. Plaintiff's recovery is accordingly barred.

12. The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including Bayer HealthCare LLC.

13. Plaintiff's claims are barred because the benefits of YAZ® and Yasmin® outweigh the risks, if any, that might be associated with the products.

14. On information and belief, the claims in the Complaint are barred in whole or in part by the learned intermediary doctrine.

15. Plaintiff's Complaint fails to state a claim upon which relief can be granted in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing and sale of YAZ® and Yasmin®, including but not limited to adequate warnings and

instructions with respect to the products' use included in the products' package inserts and other literature, conformed to the applicable state of the art. The products in question, including their labeling approved by the FDA, complied with the state of scientific and medical knowledge available at the time. Plaintiff's recovery accordingly is barred.

16. Plaintiff's claims are barred because YAZ® and Yasmin® were neither defective nor unreasonably dangerous in their design, manufacture or marketing and were reasonably safe and reasonably fit for their intended use, thereby barring Plaintiff's recovery. The warnings and instructions accompanying YAZ® and Yasmin® at the time of the occurrence or injuries alleged by Plaintiff were legally adequate warnings and instructions.

17. Plaintiff's claims are barred as a matter of law pursuant to relevant provisions of the Restatement (Third) of Torts and the Restatement (Second) of Torts, including, but not limited to, § 402A, comment k.

18. Bayer HealthCare LLC gives notice that to the extent that the sophisticated purchaser doctrine is applicable to any of the obligations in the Complaint, Bayer HealthCare LLC intends to rely upon same in defense of this action.

19. The prescription drugs YAZ® and Yasmin® complied with the applicable product safety regulations promulgated by the FDA. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of these prescription drugs, and that they were neither defective nor unreasonably dangerous. Plaintiff's recovery is accordingly barred.

20. Any claims by Plaintiff relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First and Fourteenth Amendment rights to petition the government.

21. Plaintiff's claims are barred in whole or in part because the commercial speech relating to YAZ® and Yasmin® is protected under the First Amendment of the United States Constitution and the applicable state constitution.

22. Plaintiff's claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

23. Plaintiff's claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution by reason of the federal regulation of prescription drug manufacturing, testing, marketing, and labeling.

24. Plaintiff's claims are preempted, in whole or in part, by reason of the FDA's preamble to the *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922 (Jan. 24, 2006).

25. Plaintiff cannot state a claim with regard to warnings and labeling for prescription drugs because the remedy sought by Plaintiff is subject to the exclusive regulation of the FDA.

26. This Court should abstain from adjudicating Plaintiff's claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

27. Plaintiff did not detrimentally rely on any labeling, warnings or information concerning YAZ® and/or Yasmin®.

28. Applicable law does not recognize a post-sale duty to warn in the present circumstances. Accordingly, the Complaint fails to state a claim upon which relief may be granted for inadequate post-sale marketing or post-sale duty to warn.

29. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources.

30. To the extent that Plaintiff's Complaint seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under applicable law.

31. To the extent that Plaintiff's claims have been settled or Plaintiff will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of Bayer HealthCare LLC, if any, should be reduced accordingly.

32. Plaintiff may be barred, in whole or in part, from recovery due to res judicata, collateral estoppel, or by release of claims.

33. Plaintiff's Complaint fails to state a claim upon which relief can be granted as to attorneys' fees, expenses or costs.

34. Plaintiff's Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

35. Plaintiff's Complaint fails to state a claim upon which relief can be granted for several or joint and several liability.

36. Plaintiff's claims for breach of warranty are barred because Plaintiff failed to give timely notice of any alleged breach of warranty.

37. Bayer HealthCare LLC did not sell or distribute YAZ® and/or Yasmin® to Plaintiff, and Plaintiff did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiff's claims for breach of warranty are barred by lack of privity between Plaintiff and Bayer HealthCare LLC.

38. Plaintiff's claims for breach of warranty, express or implied, are barred by the applicable state's Uniform Commercial Code or other applicable law.

39. Plaintiff's Complaint fails to state a claim for fraud, misrepresentation or omission, and fails to allege the circumstances constituting fraud with the particularity required by the Federal Rules of Civil Procedure.

40. Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

41. Bayer HealthCare LLC denies any conduct for which punitive or exemplary damages could or should be awarded and denies that sufficient evidence has been produced by Plaintiff to support or sustain the imposition of punitive damages pursuant to the applicable standard(s) of proof.

42. Permitting recovery of punitive or exemplary damages in this case would be unconstitutionally vague and/or overbroad and would violate Bayer HealthCare LLC's constitutional rights as secured by the Fifth and Seventh Amendments to the United States Constitution, would violate its rights to due process and equal protection under the Fourteenth Amendment of the United States Constitution and the prohibition against excessive fines in the United States Constitution, and would contravene other provisions of the United States and Illinois Constitutions and any other applicable state constitution.

43. Plaintiff cannot recover punitive or exemplary damages against Bayer HealthCare LLC because such an award, which is penal in nature, would violate Bayer HealthCare LLC's constitutional rights under the United States Constitution and any applicable state constitution, unless Bayer HealthCare LLC is afforded the same procedural safeguards as are criminal defendants, including but not limited to the right to avoid self incrimination, the right to forego

production and disclosure of incriminating documents and the right to the requirement of a level of proof beyond a reasonable doubt.

44. Any imposition of punitive or exemplary damages in this case would contravene the Commerce Clause of the United States Constitution, in that such an award would constitute, if imposed, an undue and unreasonable burden on interstate commerce.

45. With respect to Plaintiff's demand for punitive or exemplary damages, Bayer HealthCare LLC specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under Illinois law or other applicable law.

46. Any award of punitive or exemplary damages is barred to the extent that it is inconsistent with the standards and limitations set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008).

47. No act or omission of Bayer HealthCare LLC caused or contributed to Plaintiff's alleged injuries. Further, no act or omission of Bayer HealthCare LLC was malicious, with aggravated or egregious fraud and/or with intentional disregard of Plaintiff's rights, or evidences a flagrant disregard of human life, or was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, as alleged in the Complaint, and no act or omission of Bayer HealthCare LLC was committed with fraud, actual malice, deliberate violence or oppression, and Bayer HealthCare LLC did not act willfully, or with such gross negligence as to indicate a wanton disregard of the rights of others. Accordingly, Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

48. Plaintiff's Complaint fails to state a claim for unlawful conduct under the Illinois Consumer Fraud and Deceptive Business Practices Act because Bayer HealthCare LLC did not market, sell, label or advertise YAZ® or Yasmin®, and no act or omission of Bayer HealthCare LLC was unlawful.

49. Plaintiff's Complaint fails to state a claim for false or misleading business practices under the Illinois Consumer Fraud and Deceptive Business Practices Act because Bayer HealthCare LLC did not market, sell, label or advertise YAZ® or Yasmin®, and no act or omission of Bayer HealthCare LLC was false or misleading.

50. Plaintiff's claims are barred in whole or in part because the Illinois Consumer Fraud and Deceptive Business Practices Act is insufficiently definite to provide adequate or fair notice of the conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and the due process protections of the Illinois Constitution.

51. Plaintiff's claims are barred in whole or in part because the Illinois Consumer Fraud and Deceptive Business Practices Act unconstitutionally burdens interstate business practices relating to prescription drugs, which are heavily regulated by the FDA.

52. Plaintiff's action should be stayed or dismissed because Plaintiff has not exhausted the administrative remedies as required under the Illinois Consumer Fraud and Deceptive Business Practices Act.

53. Plaintiff's Complaint fails to properly plead Plaintiff's claims under the Illinois Consumer Fraud and Deceptive Business Practices Act with sufficient particularity.

54. Plaintiff's Complaint fails to state a cognizable claim under the Illinois Consumer Fraud and Deceptive Business Practices Act because the majority of the alleged violations of the Illinois Consumer Fraud and Deceptive Business Practices Act occurred outside of Illinois.

55. The claims asserted in the Complaint under the Illinois Consumer Fraud and Deceptive Business Practices Act are barred because the Complaint does not allege proximate causation for Plaintiff's injuries as required by *Shannon v. Boise Cascade Corp.*, 2004 WL 228958 (Ill. Feb. 5, 2004) and *Oliveira v. Amoco Oil Co.*, 201 Ill.2d 134, 776 N.E.2d 151 (2002).

56. Plaintiff's claims for punitive or exemplary damages as set forth in the Complaint are barred by 735 ILCS 5/2-604.1.

57. This Court may be an improper venue for the trial of this action.

58. This Court may not be the proper forum for the trial of this action and may not be a convenient forum for the just adjudication of Plaintiff's claims.

59. Bayer HealthCare LLC adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with Bayer HealthCare LLC's defenses pleaded in this Answer.

WHEREFORE, Bayer HealthCare LLC requests that Plaintiff's Complaint be dismissed with prejudice, that judgment be entered in favor of Bayer HealthCare LLC and against Plaintiff, and that Bayer HealthCare LLC be awarded the costs of this action, together with such other and further relief as may be appropriate.

**JURY DEMAND**

Bayer HealthCare LLC hereby demands a trial by jury on all issues so triable.

*s/ Terry Lueckenhoff*

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 19, 2009, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all attorneys of record.

*s/ Terry Lueckenhoff*